

One-Touch®

Single-Use Systems



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Disclaimer

The information in this User Guide is not intended to encompass all feasible operational scenarios of the single-use components and systems described herein given the vast array of differing applications, usage paradigms and methods contemplated by pharmaceutical end users.

The particular application, methods of use and operational conditions of single-use components and systems in your process are beyond our control. Thus, it is imperative that you test the single-use components and systems in your specific application to determine their ultimate suitability.

The components and products listed in this User Guide are designed for use in pharmaceutical and biotechnological manufacturing processes and are not to be used for any hospital or patient care.

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I. Safety

Thank you for choosing assemblies from our One-Touch® single-use systems product portfolio.



This chapter provides important safety and care information. Read this guide before using this product. Failure to follow the instructions and safety precautions in this manual could result in serious injury or death. Keep this user guide in a safe location for future reference. Meissner Filtration Products provides both customer service and technical support.

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A. Intended Use

TepoFlex® and FluoroFlex® biocontainer assemblies, as well as BioFlex® fluid path assemblies, from our One-Touch® single-use systems product portfolio are intended to be used for liquid management applications in pharmaceutical and biotechnological research, development and manufacturing by qualified personnel for in process use only and are not to be used for any hospital or patient care.

B. Safety Alert Definitions

a. Signal Words According to ANSI Z535.6-2011



DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.



WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.



NOTICE is used to address practices not related to physical injury.



Safety instructions (or equivalent) signs indicate specific safety-related instructions or procedures.

b. Signal Words According to ISO 3864

DANGER

Signal word used to indicate an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

Signal word used to indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Signal word used to indicate a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.



GENERAL WARNING SIGN

The general warning sign is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm.

C. General Safety Messages for Single-Use Assemblies

ANSI Z535.6	ISO 3864	Description
		WARNING Do not pressurize. Biocontainer assemblies are not pressure rated. Biocontainer assemblies that include a filter in their upstream fluid path must be operated so as not to pressurize the biocontainer.
		WARNING Do not exceed maximum operating temperature of 60°C or 140°F.
		WARNING Do not constrict flow on the downstream side of a pump during operation. Peristaltic pumps can introduce pressure capable of causing a loss of fluid integrity when flow is restricted.
		CAUTION Do not use single-use assemblies below minimum operating temperature of 0°C or 32°F. Biocontainer assemblies that are not designed and qualified for freeze/thaw applications, such as for example those requiring the use of protective outer rigid trays or containers, may result in fluid integrity failures. Fluid path assemblies that are not designed and qualified for freeze/thaw applications may result in fluid integrity failures.
		CAUTION Do not puncture. Single-use assemblies which are not protected from contact with sharp objects may result in fluid integrity failures.
		CAUTION Do not draw vacuum. Single-use assemblies are not rated for vacuum.
		CAUTION Do not overfill. Biocontainers are designed with a maximum overage of 10% of their stated nominal volume. Exceeding that limit may result in fluid integrity failures.

D. General Deployment and Operational Hazards

ANSI Z535.6

ISO 3864

Description



- CAUTION**
Cutting hazard. Box cutters can cause damage to your single-use assembly.
- CAUTION**
Burst hazard. Do not exceed the operating parameters for the specific filter you are using. If tubing is located upstream of the filter do not exceed operating parameters of the tubing.
- CAUTION**
Fluid Integrity hazard. Do not lean on any rigid outer container as this could cause a wall to collapse resulting in damage to a biocontainer and possible injury. Test any hanging apparatus first to ensure that it can support the weight of a full biocontainer.

C. Manifold Assemblies

Manifold Assemblies

BMR	10	06	—	S02	—	B	0253	—	01

III. Inspection Upon Receipt

Single-use assemblies are packaged in two cardboard boxes, i.e., one outer box and one or multiple inner boxes for secure transportation.

The Certificate of Quality is enclosed within the packaging. The sterilizing dosage information is available separately for download at <https://extranet.meissner.com/certificates>.

A. Guidelines for Receiving Inspection

Please refer to the following step-by-step guidelines:

1. Verify that shipping documentation is in good order.
2. Inspect the outer box for potential shipping damage and immediately report any damage to the carrier.
3. Open the outer box with caution as box cutters can cause damage to your single-use assembly.
4. Inspect inner box for potential shipping damage.
5. Verify that the Certificate of Quality is enclosed and report an absence thereof immediately to Meissner.
6. Verify Certificate of Quality with Case Label on inner box.

NOTICE

An annotated sample Case Label is featured in Appendix A. The Case Label will only feature the customer part number and customer purchase order number per specific customer request.

7. Open the inner box with caution as box cutters can cause damage to your single-use assembly.
8. Inspect single-use assemblies for potential shipping damage.
9. Verify Certificate of Quality with Product Label.

NOTICE

An annotated sample Product Label is featured in Appendix A. The Product Label will only feature the customer part number and customer purchase order number per specific customer request. If the product has been requested as non-sterile, it will be noted as such in lieu of the irradiation dot.

10. Verify the quantity of single-use assemblies received and immediately report any shortfall to Meissner.

IV. Unpacking Your Biocontainer Assembly

Single-use assemblies are manufactured in an ISO class 7 cleanroom and vacuum packaged in two polyethylene bags. The single-use assembly is sealed directly inside the inner poly-bag, which is sealed inside the outer poly-bag. Certain items may include additional packaging to provide protection during shipment. For more information in this regard see chapter VI.

Once packaged, single-use assemblies are gamma irradiated before being shipped unless otherwise requested.

NOTICE

If the product has been requested non-sterile, it will be noted as such on the Product Label. See Appendix A for reference.

A. Pre-Use Inspection

Please refer to the following step-by-step guidelines:

1. Remove desired quantity of single-use assemblies from inner box.
2. Verify that the packaging is in good order.
3. Recycle or discard packaging according to local regulations as appropriate.
4. Verify that the expiration date on the Product Label for each single-use assembly has not passed. See Appendix A for reference.
5. Record the lot and/or serial number along with any other information that you need for your batch record as appropriate. Meissner's peel and stick label (which is located on the outside of the inner bag) will save time and help to eliminate human error in transferring data to documentation.

B. Guidelines for Unpacking

Please refer to the following step-by-step guidelines (continued on the next page):



Position a safety cutter or other cutting device so that you will only open the outer poly-bag; carefully cut open the outer poly-bag.

NOTICE

Often after removing the outer poly-bag the single bagged product will be transferred to a controlled space, e.g. a cleanroom, for subsequent handling.



Carefully remove the inner poly-bag from the outer poly-bag and retain peel and stick label for your records should you choose to do so.



Position a safety cutter or other cutting device so that you will only open the inner poly-bag. Carefully cut open the inner poly-bag, ensuring that you do not damage your single-use assembly.



You now have access to your single-use assembly.



Carefully remove your single-use assembly from the inner poly-bag.

V. Deploying Your Biocontainer Assembly

A. Pre-Deployment Inspection

1. Verify clamp positions and leave them open or close them, depending on your application.

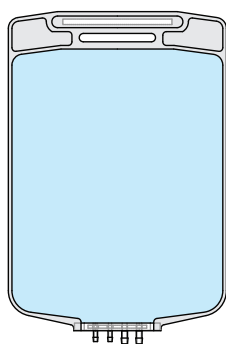
NOTICE

Single-use assemblies arrive with clamps open to prevent compression set on tubing that may hinder functional deployment and/or operation.

2. Verify that all tubing end treatments are secured as required for your application.

B. 2D End-Ported Biocontainer Deployment

2D end-ported biocontainers are designed to be operated in a hanging or pillow position (either lay it flat or at the desired angle). See figures below for examples.



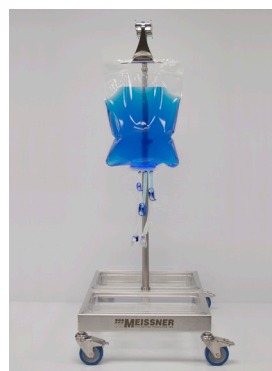
2D end-ported biocontainer



2D end-ported biocontainer in a flat pillow position



2D end-ported biocontainer in angled pillow position



2D end-ported biocontainer in hanging position utilizing FlexCessory™ cart & hanger



2D end-ported biocontainer in hanging position utilizing the universal lab stand

a. Hanging Your Biocontainer

- i. Meissner's FlexCessory™ dual end-ported biocontainer cart provides security when deploying end-ported biocontainer assemblies. The stand can support up to two 20 L end-ported biocontainers and is adjustable, via a center post clamp, to a height of 72 inches. Biocontainer assemblies can be directly supported on the notched head of the cart or hung from the ergonomically designed stainless steel FlexCessory™ hanger.
- ii. Meissner's universal lab stand is designed to support up to one 20 L biocontainer on a flat workbench or counter. The stand can be used with any 1" shaft collar attachment such as the biocontainer hanger shown in the photo above.

b. Deploying Your Biocontainer in a Tray or Other Support Device

Carefully position biocontainer in or on support device and ensure that the ports on the container are in the correct position for your specific application.

NOTICE

Fluid paths should be positioned to enable unrestricted transfer of fluid and should not be obstructed by the biocontainer.

c. Filling Your Biocontainer

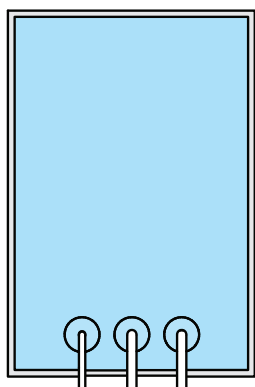
Once your biocontainer is positioned and supported, decide which clamps should remain open and which should be closed, and subsequently which process connections need to be engaged based on the intended application. See Chapter VI for more information regarding process connections.

C. 2D Face-Ported Biocontainer Deployment

2D face-ported biocontainers are designed to be deployed and operated in a pillow position (either lay it flat or at the desired angle). Support devices include the following but are not limited to: lab tables, shelves, trays, other smooth, flat or slightly angled surfaces. See the figures below for examples with 2D face-ported biocontainers.

NOTICE

For larger 2-D face-ported biocontainers (i.e. 50-200L), cylindrical drums can often be used as support devices. Contact Meissner if you have specific questions in this regard.



2-D face-ported biocontainer



2-D face-ported biocontainer in a flat pillow position



2-D face-ported biocontainer in angled pillow position



2-D face-ported biocontainer supported by cylindrical drums

a. Deploying Your Biocontainer

Ensure that the ports on the container are in the correct position for your specific application.

NOTICE

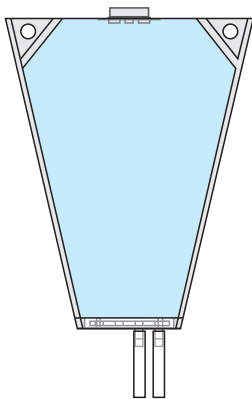
Fluid paths should be positioned to enable unrestricted transfer of fluid and should not be obstructed by the biocontainer.

b. Filling Your Biocontainer

Once your biocontainer is positioned and properly supported, decide which clamps should remain open and which should be closed, and subsequently which process connections need to be engaged based on the intended process application. See Chapter VI for more information regarding process connections.

D. FlexFill® Biocontainer Deployment

FlexFill® biocontainer assemblies are designed for applications requiring fast and dependable aseptic transfer of liquid volumes less than or equal to 5L. Its large screw-cap port allows for rapid and convenient filling in an aseptic environment (e.g. in a laminar flow hood) using the portable stainless steel FlexCessory™ stand.



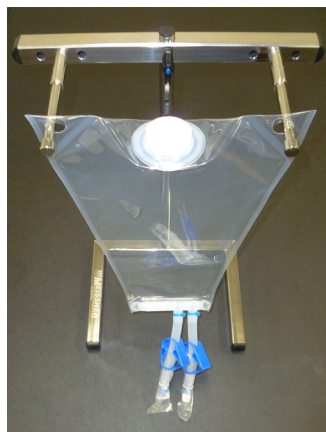
FlexFill® biocontainer



FlexFill® biocontainer supported on FlexCessory™ stand

FlexFill® Mixing systems have been optimized for small volume powder-liquid and liquid-liquid mixing applications. The distinctive blended shape of the FlexFill® biocontainer in conjunction with the unique porting locations featured on the mixing assemblies provide robust mixing action when used with a suitable peristaltic pump. FlexFill® mixing assemblies support aseptic processing when deployed using the portable stainless steel FlexCessory™ stand in a laminar flow hood or when specified with sterile and/or aseptic fluid path connection options.

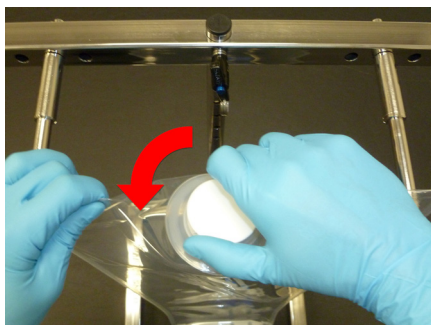
Please refer to the following step-by-step guidelines (continued on the next page):



Place FlexFill® biocontainer on the stand and adjust to accommodate screw cap removal and filling. Adjust support pins on stand so that slack on the top of the FlexFill® is minimized without stretching the film.

NOTICE

Decide which clamps should remain open and which should be closed, and subsequently which process connections need to be engaged based on the intended process application. See Chapter VI for more information regarding process connections.



The screw cap is hand tightened to maintain aseptic conditions and may require moderate force to remove. Grasp a corner of the FlexFill® biocontainer at the cross seam with one hand while turning the screw cap counter-clockwise with your other hand.

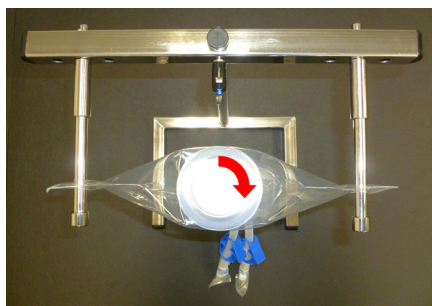
NOTICE

The following should be completed under a laminar flow hood to maintain aseptic process conditions

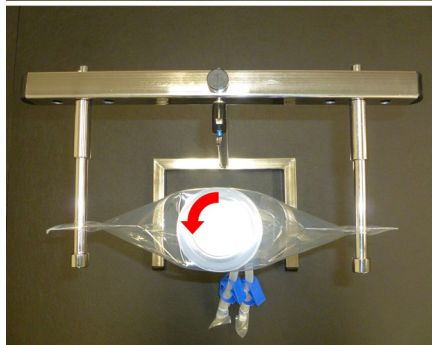


Fill your FlexFill® biocontainer in accordance with your internal procedures or practices regarding aseptic handling.

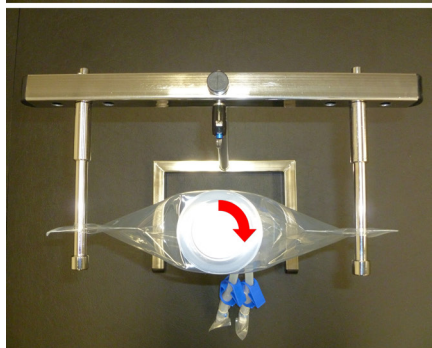
If the threads or sealing surface of the port become contaminated during the filling operation, clean the area with an appropriate antimicrobial disinfectant according to your internal procedures or practices.



Manually install the screw cap by turning clockwise until it seats using moderate force.



Manually loosen the screw cap by turning it counter clockwise until it just breaks free from its friction point.



Immediately, and in the same motion, manually retighten the screw cap using moderate force.

NOTICE

This second tightening action compresses the screw cap liner creating a seal which is 5 to 7 times stronger than a single tightening alone while eliminating the need for slip agents or other plastic additives.



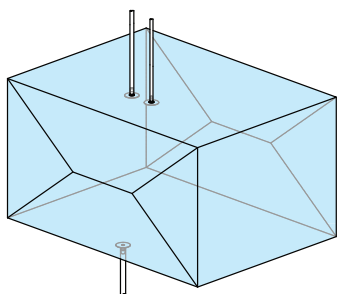
If using a FlexFill® mixing assembly, deploy recirculation loop in accordance with your internal procedures and practices while adhering to the peristaltic pump manufacturer's instructions.

NOTICE

The use of tubing in a peristaltic pump which is either incorrectly sized and/or manufactured from inappropriate material, can lead to premature tubing failure.

E. 3D Biocontainer Deployment in Rigid Outer Containers

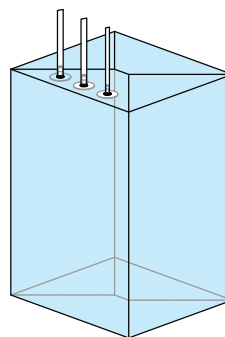
Rigid Outer Containers (ROCs) offer support for 3D biocontainers and larger 2D face-ported biocontainers. See the figures below for examples of 3D biocontainers supported by ROCs.



3D top and bottom ported biocontainer



3D biocontainer supported by a FlexStation® ROC



3D top-ported biocontainer designed for drum deployment



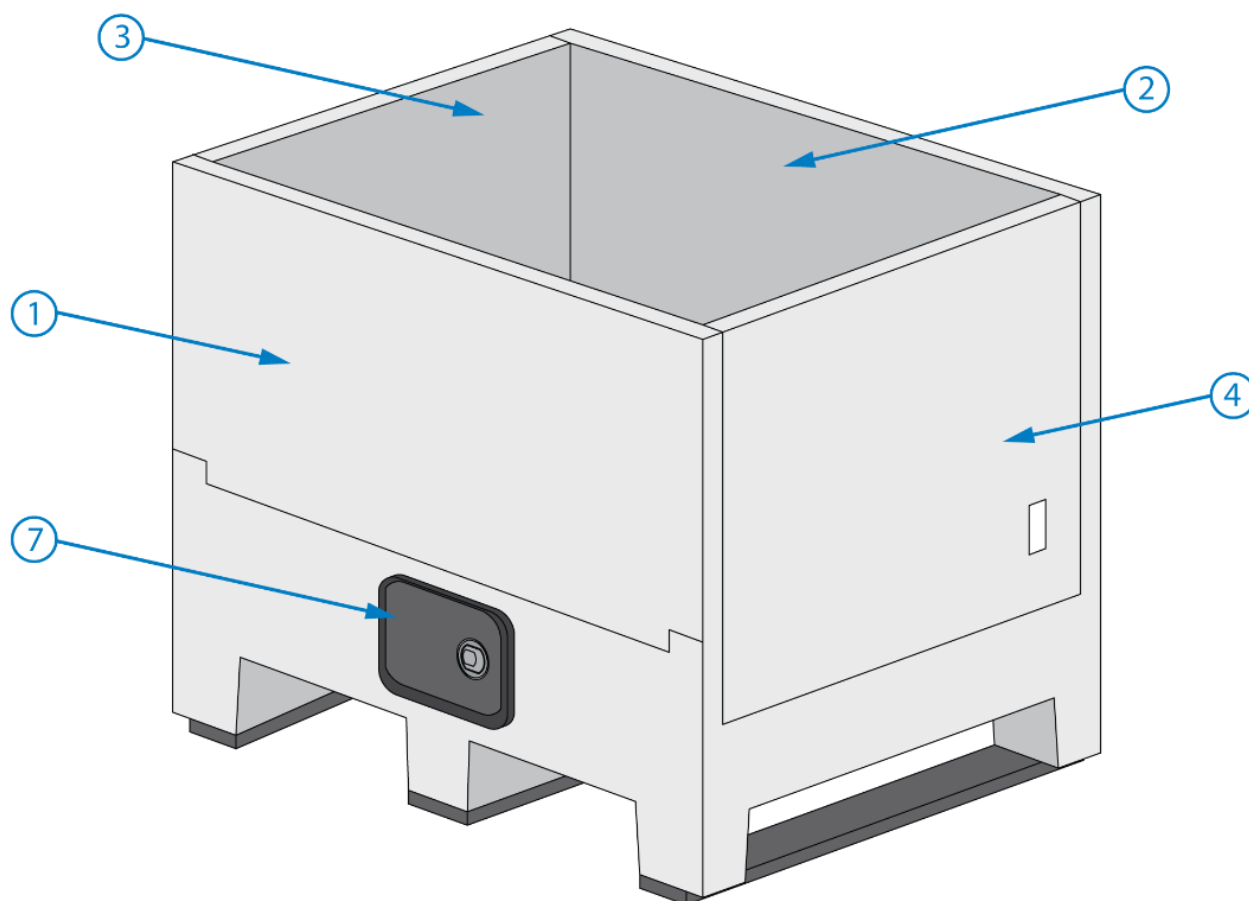
3D biocontainer supported by QuaDrum® on dolly

a. 3D Biocontainer Deployment in FlexStation® Rigid Outer Containers

3D biocontainers can be supplied with top and/or bottom ports. A rigid outer container (ROC) with bottom porting allows for easy product drain utilizing gravity, whereas top ported biocontainers typically require a peristaltic pump to evacuate.

100-500 L FlexStation® ROC's have either a false bottom or a false wall for access to bottom porting and associated fluid path storage.

i. FlexStation® 100 and 200

**FlexStation® 100 and 200 Orientation for Biocontainer Deployment**

ITEM	DESCRIPTION
1	Front Wall - Front of the FlexStation® ROC
2	Back Wall - Back of the FlexStation® ROC
3	Left Side Wall - The left-hand side of the FlexStation® ROC
4	Right Side Wall - The Right-hand side of the FlexStation® ROC
5	False Bottom - The inner biocontainer support tray of the FlexStation® ROC (not pictured)
6	Collapsible Support Frame (not pictured)
7	Bottom Drain Access Door

Verify that your biocontainer and FlexStation® are compatible:

1. 200 L biocontainer assemblies designed for the FlexStation® are used only with FlexStation® 200 units.
2. 100 L biocontainer assemblies designed for the FlexStation® 100 can be used with either the FlexStation® 100 or 200.

3. The FlexStation® can be easily identified by its nameplate but can also be verified by the distance that the false bottom is located from the floor of the ROC:
 - a. A FlexStation® 200 will have a false bottom that is approximately 4 inches from the bottom of the ROC when erected.
 - b. A FlexStation® 100 will have a false bottom that is approximately 10 inches from the bottom of the ROC when erected.

Prepare the FlexStation® to receive a biocontainer assembly:

1. Remove the lid from the ROC and erect the walls.
2. Remove the plastic false bottom.
3. Erect the false bottom rack.
 - a. Lift the rack above the ROC floor.
 - b. Rotate the legs outward so that the feet contact both the side and the floor of the ROC.

NOTICE

Step 3 is most easily accomplished by first rotating the back legs outward simultaneously and then, while resting the rack on the back legs, rotating the front legs outward simultaneously.



False bottom rack in place



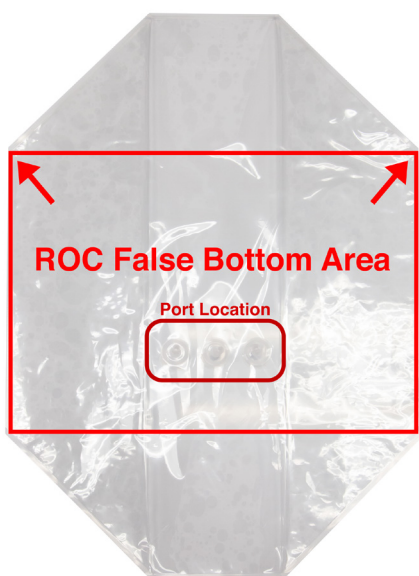
False bottom tray in place

4. Reinsert the false bottom tray.
 - a. Orient the tray with the sides pointed up and the hole closest to the front of the ROC (nearest the false bottom door).
 - b. Press down on the corners of the false bottom tray to make sure the tray is seated flat against the false bottom rack.

Orient and install biocontainer assembly:

1. FlexStation® compatible biocontainer assemblies are packaged in a rectangular format. When opened and laid flat, they form an octagon. This octagon has two long side edges that are four film layers thick (identified as Left and Right in biocontainer octagon figure) and a front and back edge that are two film layers thick with diagonal corners in between.

- a. The short sides of the biocontainer (two layers thick) will fold up against the front and back walls of the ROC.
- b. The long sides of the biocontainer (four layers thick) will meet the left and right sides of the ROC when laid flat against the false bottom.
- c. Of the eight corners of the octagon, the four corners that are four film layers thick should meet each corner of the ROC at the false bottom.
- d. Note the section of the biocontainer (laying flat in the FlexStation® ROC) that is only two film layers thick. This will appear as a strip of more transparent material running from front to back of the ROC. The biocontainer ports will be centered from left to right in this strip.



100 L or 200 L Biocontainer Octagon



100 L or 200 L Biocontainer in FlexStation® ROC

2. If a top-ported biocontainer assembly is being installed:
 - a. Install the assembly per the octagon orientation making sure that all porting is facing up.
 - b. Verify that no tubing is trapped by the biocontainer. No tubing should be running between the ROC walls and the biocontainer.
3. If a top and bottom-ported biocontainer assembly is being installed:
 - a. Locate the bottom port, which is offset to meet the hole in the false bottom tray.
 - b. Route all bottom tubing/fittings through the hole in the false bottom tray and out the false bottom door, taking care not to stress the biocontainer during installation.



Tubing routed through hole in false bottom tray

- c. Complete installation of the biocontainer assembly per the octagon orientation previously described.
- d. Verify that no tubing is trapped by the biocontainer. No tubing should be running between the ROC walls and the biocontainer.

Fill the biocontainer assembly:

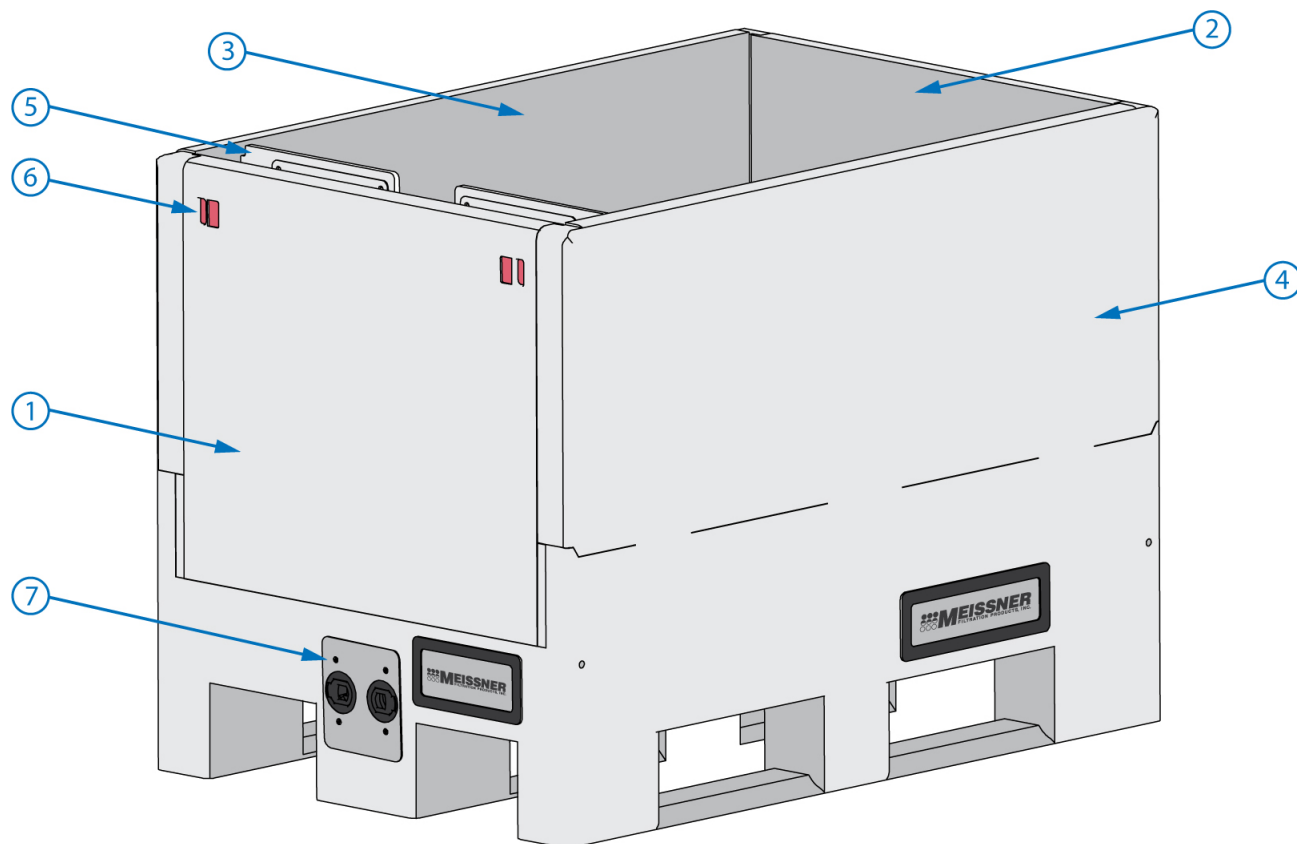
1. For porting connections on the top of the biocontainer, carefully reach over the front of the ROC for access.
2. The biocontainer may be filled from either top or bottom ports.

NOTICE

Fluid paths should be positioned to enable unrestricted transfer of fluid and should not be obstructed by the biocontainer.

- a. The biocontainer will self-deploy as it is filled.

ii. FlexStation® 500

**FlexStation® 500 Orientation for Biocontainer Deployment**

ITEM	DESCRIPTION
1	Front Wall - Front of the FlexStation® 500 ROC
2	Back Wall - Back of the FlexStation® 500 ROC
3	Left Side Wall - The left-hand side of the FlexStation® 500 ROC
4	Right Side Wall - The Right-hand side of the FlexStation® 500 ROC
5	False Bottom - The inner biocontainer support tray of the FlexStation® 500 ROC
6	Wall Release Latches
7	Bottom Drain Access Door

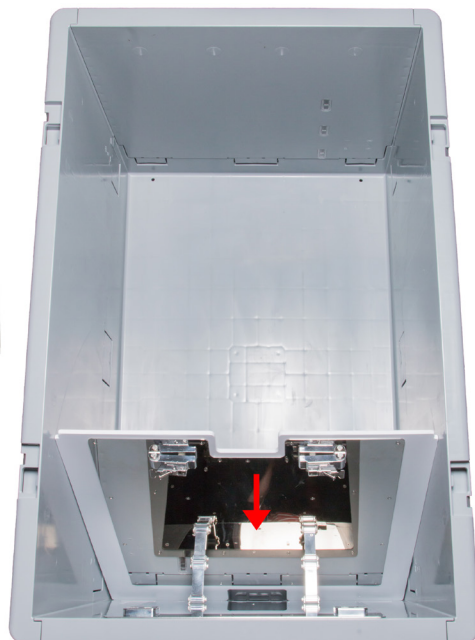
Verify that your biocontainer and FlexStation® are compatible:

1. Only 500 L biocontainer assemblies are used with FlexStation® 500 units.
2. The FlexStation® can be easily identified by its nameplate but can also be verified by the interior “footprint” or “base” dimensions of the ROC:
 - a. A FlexStation® 500 will be 102cm x 72cm (40" x 28").
3. The biocontainer assembly can be identified by its label.

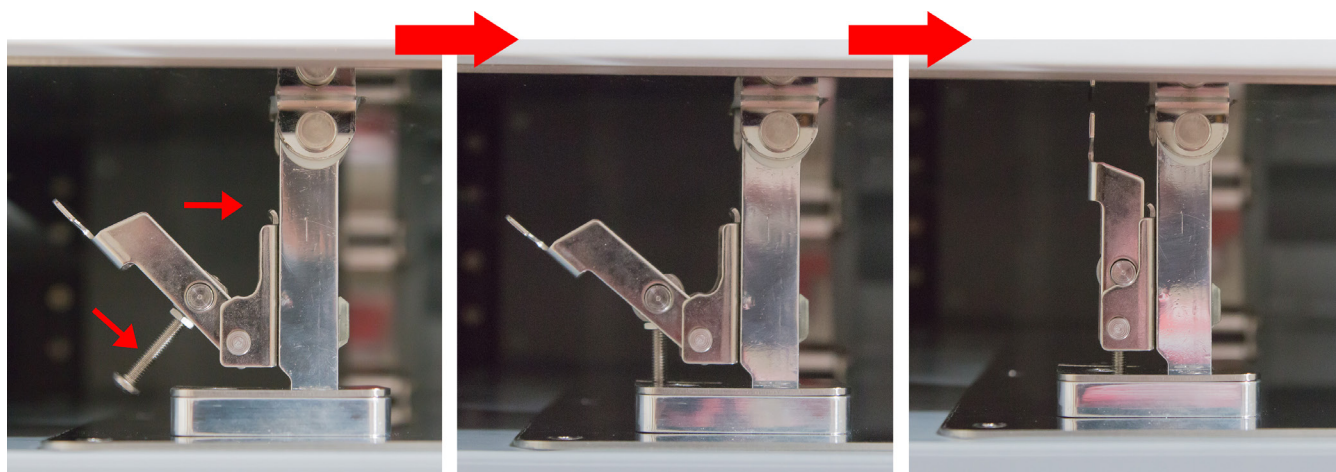
Prepare the FlexStation® to receive a biocontainer assembly:

1. Remove the lid from the ROC and erect the walls.
 - a. Open the front wall last, making sure the red latches are secure.

2. Erect and latch the false wall.
 - a. The false wall will be leaning away from the front wall.
 - b. Move the top of the false wall toward the front until the wall clears the stop blocks at the very bottom of the bin.



- c. Move the top of the false wall back away from the front until there is enough room for the upper links to rotate out.
- d. Insert the links into their rectangular receivers (both the left and right links should be inserted simultaneously).
- e. Insert the draw-latch pins into their slots and latch latches



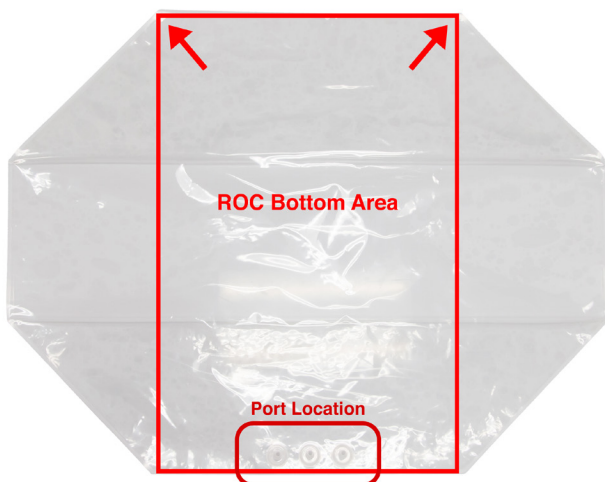
Latching the false wall

NOTICE

The latches should snap closed with only light pressure. If the latches will not close, or do not stay closed, the draw-latch pins may require adjustment.

Orient and install biocontainer assembly:

1. FlexStation® compatible biocontainer assemblies are packaged in a rectangular format. When opened and laid flat they form an octagon. This octagon has two long side edges that are four film layers thick and a left and right edge that are two film layers thick with diagonal corners in between.
 - a. The short sides (left and right) of the biocontainer (two layers thick) will fold up against the left and right walls of the ROC.
 - b. The long sides of the biocontainer (four layers thick) will meet the front and back sides of the ROC when laid flat against bottom.
 - c. The back corners of the biocontainer should be located at the bottom back corners of the ROC.
 - d. The biocontainer ports will be centered at the front of the ROC and will meet with the bottom drain relief in the floor of the ROC.



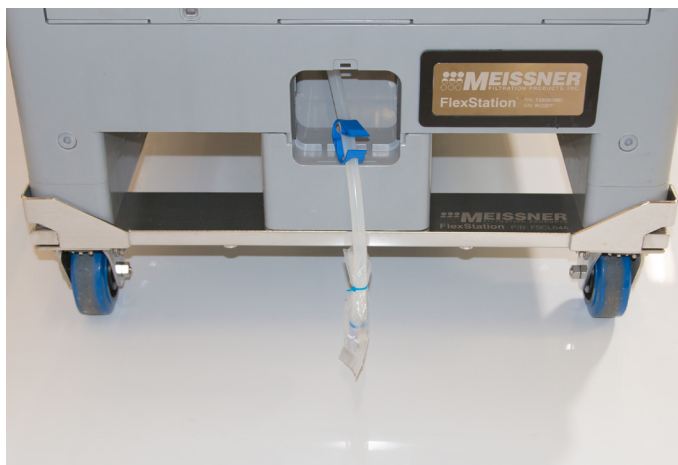
500L Biocontainer Octagon



500L Biocontainer in FlexStation® ROC

2. If a top-ported biocontainer assembly is being installed:
 - a. Install the assembly per the octagon orientation described previously making sure that all porting is facing up.
 - b. Verify that no tubing is trapped by the biocontainer. No tubing should be running between the ROC walls and the biocontainer.

3. If a top and bottom-ported biocontainer assembly is being installed:
 - a. Locate which port your organization has designated as the bottom port and verify that this port is facing down.
 - i. If a standard biocontainer assembly is used, the bottom port will be a single larger port.
 - b. Verify that no tubing is trapped by the biocontainer. No tubing should be running between the ROC walls and the biocontainer.
 - i. Take care not to stress the biocontainer during installation.



Tubing routed through relief in bottom of false wall and out the access door

- c. Complete installation of the biocontainer assembly per the previously described octagon orientation.

Fill the biocontainer assembly:

1. For porting connections on the top of the biocontainer, carefully reach over the front of the ROC for access.
2. The biocontainer may be filled from either top or bottom ports.

NOTICE

Fluid paths should be positioned to enable unrestricted transfer of fluid and should not be obstructed by the biocontainer.

- a. The biocontainer will self-deploy as it is filled.

iii. **Additional FlexStation® Information**

FlexStation® 1000 ROC's are available for biocontainer assemblies with volumes larger than 500 L. Please contact Meissner for detailed product information.

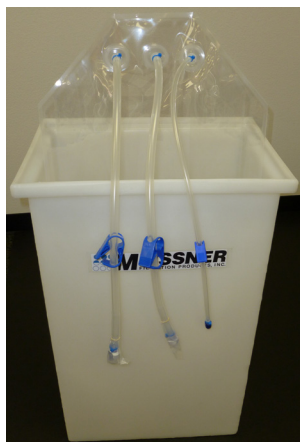
Support and transfer of FlexStation® ROC's can be accomplished with Meissner FlexStation® specific mobile carts or hand pallet truck. Please contact Meissner for detailed support product information.

b. 3D Biocontainer Deployment in QuaDrum® Rigid Outer Containers

Please follow the step-by-step instructions:



Hold the biocontainer at the top and unfold it as shown.

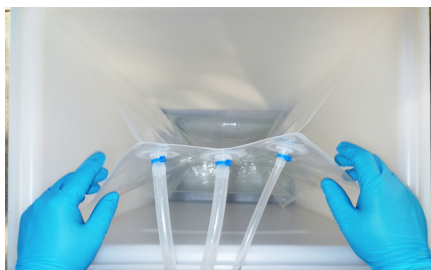


Place the biocontainer, top ports up, in the drum with tubing on the outside.

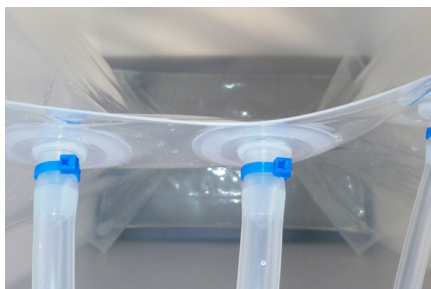
NOTICE

Decide which clamps should remain open and which should be closed, and subsequently which process connections need to be engaged based on the intended application.

If using a dolly, place the drum on dolly before biocontainer deployment.



Position the biocontainer so that the four gusseted corners of the biocontainer fit into the corners of the drum.



While filling the biocontainer, ensure that placement of the gusseted corners is secure for approximately the first five liters.



The biocontainer is designed to self-deploy however due to the high aspect ratio of the QuaDrum® it is recommended to monitor the filling process and adjust the biocontainer when necessary.

c. Third Party Rigid Outer Containers

Meissner Filtration Products designs custom biocontainers that fit in third party rigid outer containers such as industry standard cylindrical drums; however, it is ultimately the customer's responsibility to correctly deploy our biocontainers in third party outer containers. It's imperative that custom biocontainers are tested for their specific deployment and use.

Please consult Meissner if you have further questions regarding the use of third party ROC's.

VI. Operating Your Single-Use Assembly

A. Supplementary Packaging

Single-use assemblies may include supplementary packaging items to provide tamper evidence and/or additional protection during shipment. The three most common types of supplementary packaging are identified below however this is not an exhaustive list. Please consult Meissner if you have any questions pertaining to supplementary packaging not covered here.

a. Vinyl Dust Caps

Some end fittings are supplied with vinyl dust caps as a precaution. For example, many simple Luer end-fittings and some TC connections utilize these. Simply remove the dust cap when access to a given connection is required.

b. Bubble Wrap Poly-Bags

Filters and longer fluid paths with bulky componentry are often placed in sealed bubble wrap poly-bags to provide additional protection. These can easily be removed during deployment of the associated single-use assembly.

c. Tamper Evident Poly-Bags

Quick connectors, aseptic connectors and some other tubing end-treatments may include tamper evident re-closable poly-bags secured with a cable tie. To gain access to the process connection simply remove the perforated tamper evident plastic strip and open the poly-bag via the re-closable seal. The poly-bag can be pushed back away from the fluid path and the connection then made.

B. General Process Connections

a. Quick Connectors

Quick disconnect couplings (QDC's) are commonly used to accomplish 1/4" – 1/2" inner diameter tubing connections. These are not considered aseptic connectors, however they can be operated aseptically given the proper environment and technique. There are two general types of QDC's; MPC fittings accommodate flow paths between 1/8" and 3/8" inner diameter while MPX fittings can be used with 3/8" and 1/2" inner diameter flow paths.



QDC's are delivered with caps or plugs to close off the fluid path.



When ready to make a connection, ensure that fluid flow is restricted accordingly and remove cap and plug according to your internal procedures and practices.



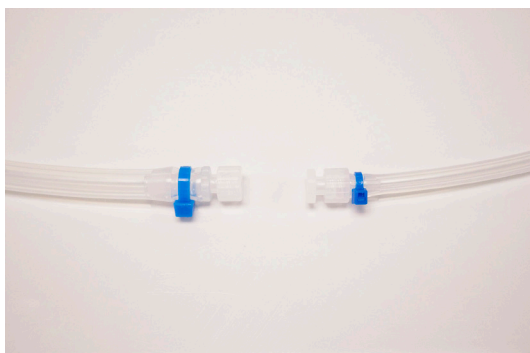
To make a connection, simply push the coupling insert into the coupling body until you hear an audible "click".



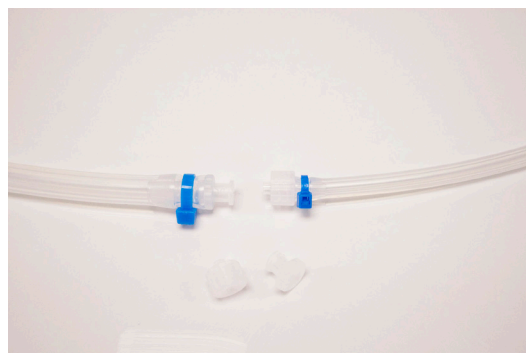
To disconnect, ensure that fluid flow is restricted accordingly and depress white latch on coupling body to pull coupling insert out.

b. Luer Connectors

Luer connectors are typically used for sampling operations and small volume fluid transfer applications.



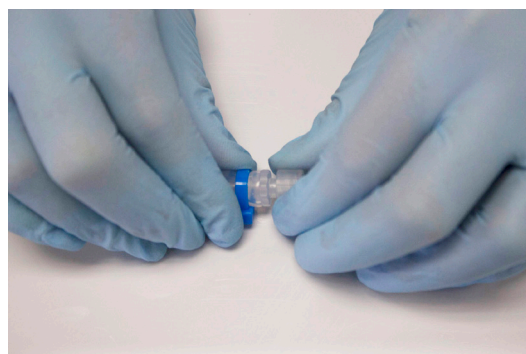
Luer connectors are delivered with caps or plugs to close off the fluid path.



When ready to make a connection, ensure that fluid flow is restricted accordingly and remove cap and plug according to your internal procedures and practices.



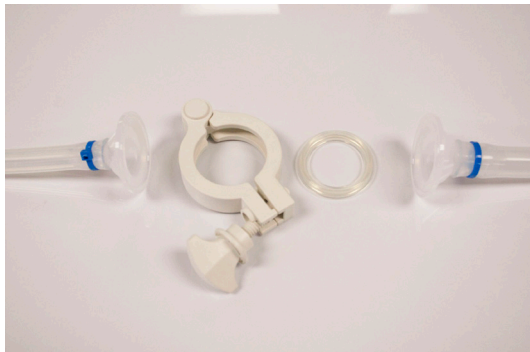
To make a connection, hold one connector with your left hand and turn opposite connector clockwise with your right hand.



To disconnect, ensure that fluid flow is restricted accordingly and hold one connector with your left hand and turn opposite connector counter-clockwise with your right hand.

c. Sanitary Flange Fittings

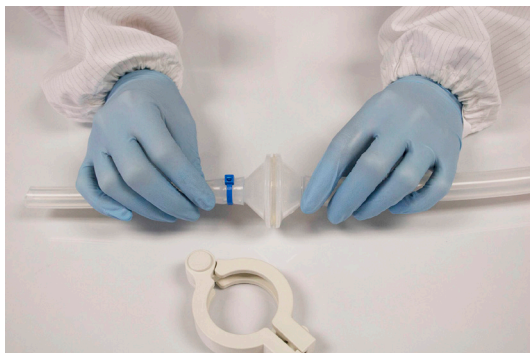
Sanitary flange fittings are often used as a connection between single-use systems and traditional processing equipment. They are suitable for high pressure applications when used in conjunction with high pressure tubing and high pressure hose barb connectivity.



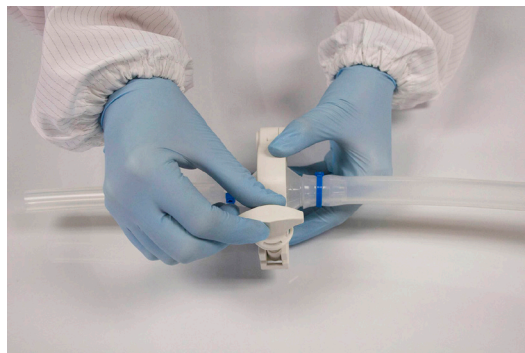
Sanitary flange fittings can be delivered with either a vinyl dust cap or secured with a blind cap, gasket and clamp. To connect two sanitary flange fittings you'll need one gasket and one clamp.



When ready to make a connection, ensure that fluid flow is restricted accordingly, remove any protective covering and place silicone gasket into ridge on one sanitary flange.



Connect the flanges together with the gasket between them.



Apply clamp around the outside of the flanges and tighten the butterfly screw by turning it clockwise. To remove clamp, turn butterfly screw counter-clockwise.

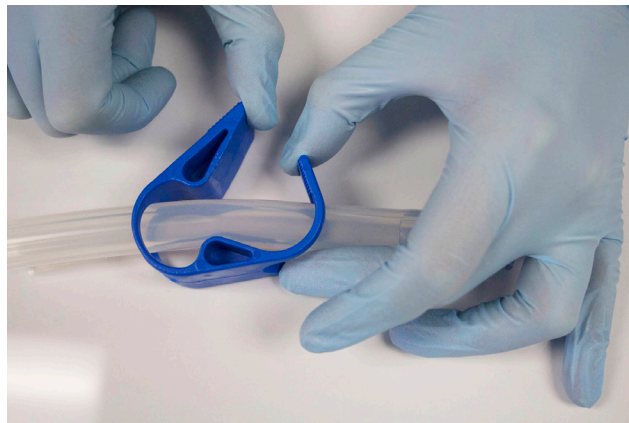
C. Controlling Flow

a. Clamps

Ratcheting pinch clamps are commonly used for controlling fluid flow and are compatible with most standard tubing.



To restrict or stop fluid flow, pinch clamp together.



To allow fluid flow, open clamp by pulling bottom of clamp so that ratchet is released and pull both ends as shown.

b. Valves

Single use valves can be used as clamps to shut off fluid flow or as valves to control flow rates. For high pressure applications Meissner recommends the use of heavy duty valves like the one in the figures below in conjunction with braid reinforced silicone tubing.



To restrict or stop fluid flow, tighten butterfly screw by turning clockwise.



To allow fluid flow, loosen butterfly screw by turning counter-clockwise.

D. Aseptic Process Connections

a. Single-Use to Single-Use Aseptic Connections

There are two general types of aseptic connectors that Meissner recommends; AseptiQuik® connectors, which utilize a coupling insert and a coupling body, and AseptiQuik® G connectors, which are genderless. Alternatively, tube welders can be used to make aseptic process connections.

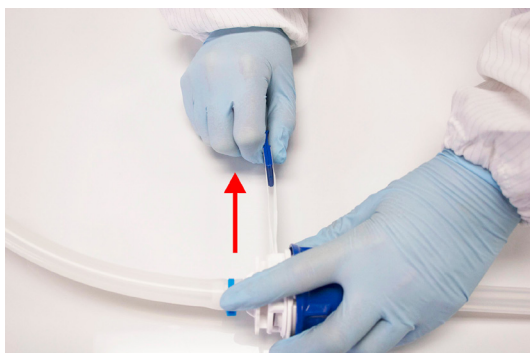
i. Aseptic Connectors



AseptiQuik® connectors are delivered with protective caps. Remove these caps when ready to make an aseptic connection.



Ensure that fluid flow is restricted accordingly. Line up blue tabs and click the coupling insert into the coupling body.



Pull blue membrane tabs out together.



Hold coupling body (white connection) in place and twist coupling insert blue collar clockwise until you hear a click.

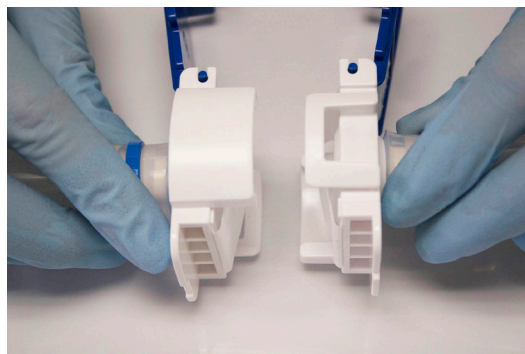
NOTICE

For more information about the AseptiQuik® refer to the Colder Products Company® website at www.colder.com.

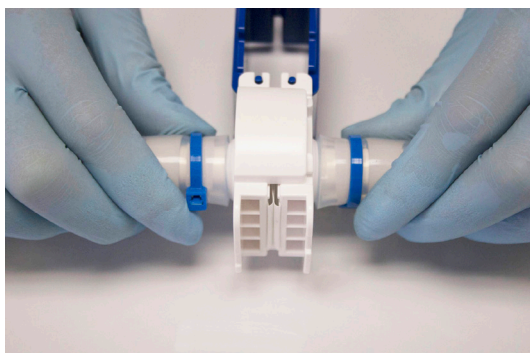
ii. Genderless Aseptic Connectors



AseptiQuik® G connectors are delivered with their blue membrane pull tabs covering the connections.



When ready to make an aseptic connection, ensure that fluid flow is restricted accordingly and open tabs so that they line up.



Click the connections together.



Pull blue membrane tabs out together.

NOTICE

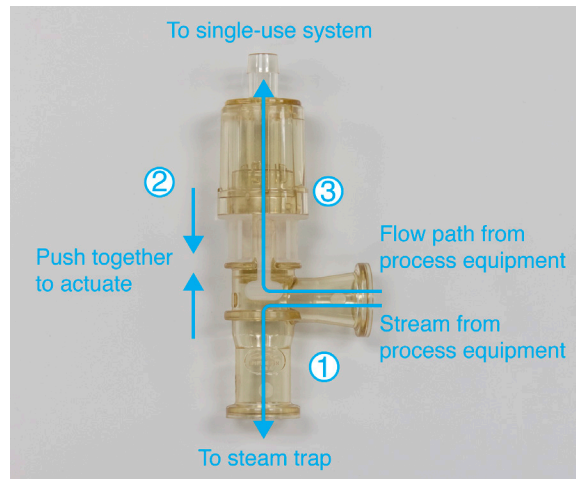
For more information about the AseptiQuik® G refer to the Colder Products Company® website at www.colder.com.

iii. Tube Welders

Tube welders are used to aseptically connect thermoplastic elastomer (TPE) or PVC tubing materials. Tubing that is specified to be welded will typically terminate with a hose barb plug or a sealed end. Refer to your tube welder manufacturer for safety information and user instructions.

b. Single-Use to Multiple-Use Aseptic Connections

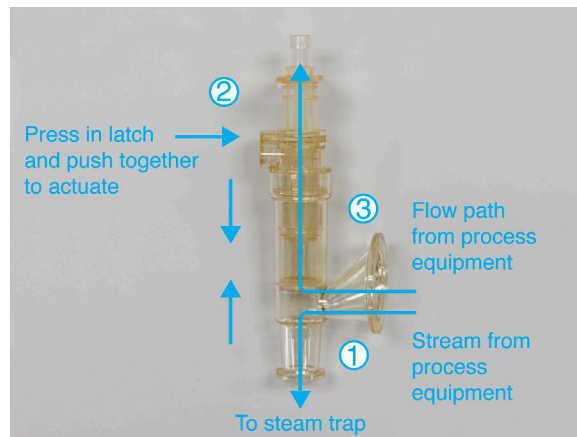
i. Steam-Thru® Connectors (STC's)



Process Flow Diagram for Steam-Thru®

1. To sterilize the connection, allow steam to flow from the process equipment through the STC into a steam trap.
2. Remove protective sleeve when ready to disconnect from the steam trap and push together to actuate.
3. Establish flow between process equipment and single use system.

ii. Steam-Thru® II Connectors (STC II's)



Process Flow Diagram for Steam-Thru® II

1. To sterilize the connection, allow steam to flow from the process equipment through the STC II into a steam trap.
2. Remove protective sleeve when ready to disconnect from the steam trap. Depress latch and push together to actuate. The STC II is now in the "flow position."
3. Establish flow between process equipment and single use system.
4. To return to "sterilization position", depress latch and move valve back up to original location.

NOTICE

For more information about Steam-Thru® and Steam-Thru® II connectors refer to the Colder Products Company® website at www.colder.com.

E. Aseptic Process Disconnections

a. HFC39 Series Connectors

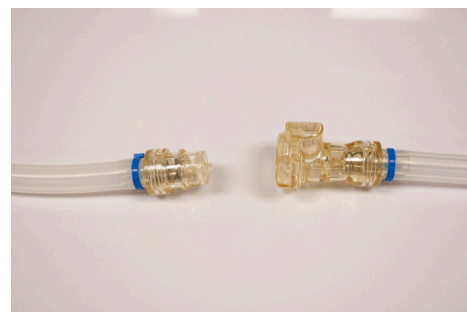
The HFC39 series connectors are designed to shut off the flow path when disconnected, providing single-use aseptic disconnect functionality. These connectors are designed for single actuation; i.e. do not reconnect them.



HFC39 series connectors are delivered connected, ensuring sterility.



When ready to make an aseptic disconnection, depress thumb latch and pull connectors apart.



Do not reconnect once HFC39 connectors have been disconnected.

NOTICE

For more information about HFC39 series connectors refer to the Colder Products Company® website at www.colder.com.

b. Tube Sealers

Tube sealers are used to aseptically disconnect tubing. TPE tubing can be sealed with thermal equipment. PVC and EVA tubing can be thermally sealed or RF welded. Refer to your tube sealer manufacturer for safety information and user instructions.

F. Effecting Fluid Transfer of Liquids

The two most common methods of affecting a fluid transfer to, from, or through a single-use system are via gravity and via the use of a peristaltic pump. Typically peristaltic pumps require specific size tubing in order to function. An abbreviated table is provided below. However, please consult your pump manufacturer's operating manual for specific tubing size and material recommendations.

Peristaltic Pump Tubing Sizing Chart						
Tubing Size		Masterflex®		Watson Marlow		
ID x OD	Number	L/S® High Performance	I/P® Precision	520R	520R2	620R
1/8" x 1/4"	16			x		
3/16" x 5/16"	25			x		
3/16" x 3/8"	15	x			x	
1/4" x 3/8"	17			x		
1/4" x 7/16"	24	x			x	
1/4" x 1/2"	26		x			x
3/8" x 9/16"	36	x				
3/8" x 5/8"	73		x			x
1/2" x 3/4"	82		x			x

NOTICE

The use of tubing in a peristaltic pump which is either incorrectly sized and/or manufactured from inappropriate material, can lead to premature tubing failure.

G. Taking Samples

a. Sampling and Injection Sites

There are multiple sampling and injection options available. Meissner typically recommends swabable valves or needle free connectors, which are designed as sample sites that can be utilized without a needle. First swab the silicone seal then connect a male luer syringe to take a sample according to your internal procedures or practices.

i. Swabable Valve / Needleless Injection Site



Swabable valves are delivered with a protective cap. When ready to make a connection, remove cap.



Connect male luer syringe to valve.



Take sample or add to single-use system according to your internal procedures or practices.

NOTICE

For more information about the swabable valve refer to the Halkey-Roberts Corporation website at www.halkeyroberts.com.

ii. NeedleFree Connector



NeedleFree connectors are delivered with a protective cap. When ready to make a connection, remove cap.



Connect male luer syringe to valve.



Take sample or add to single-use system according to your internal procedures or practices.

NOTICE

For more information about the Clave® NeedleFree Connector, refer to the ICU Medical website at www.icumed.com.

H. Use of Filters

a. Operating Instructions for Filters

The following instructions are fairly broad as there are many different types and configurations of filters. More specific usage instructions for Meissner filters can be downloaded by selecting the corresponding filter Green Doc at www.meissner.com/greendocs. You can also contact Meissner Technical Services for more information and assistance.

1. Secure the inlet and outlet of the filter as required by the single-use assembly design and its usage.



Filter with hose barbs on inlet and outlet



Filter with sanitary fittings on inlet and outlet

2. Slowly initiate flow through the filter.
3. If venting is necessary, position the filter so the vent opening points upward and slowly open the vent. Continue to vent until liquid exits the vent or all air is expelled.
4. Gradually increase the pressure or flow rate to the value qualified by your internal procedures.
5. Monitor the filter during the process for pressure build up and vent as necessary.
6. When filtration is complete stop flow to filter.
7. In the case of a fluid filtration process step, filter(s) will generally need to be aseptically disconnected from the downstream process within 8 hours of filtration.

NOTICE

Refer to filter manufacturer's technical data sheets for filter specific information. Meissner Filtration Products provides filter data sheets called, "Green Docs" at www.meissner.com.

b. Pre-use Integrity Testing

Certain single-use systems can be designed to accommodate pre-use integrity testing functionality. The specifications for pre-use integrity tests vary depending on the assembly and type of filter. Please contact Meissner Technical Services for more information.

c. Post-use Integrity Testing

Disconnect filters from the single-use assembly and post-use integrity test according to your internal procedures and practices and the filter specifications. Please contact Meissner Technical Services for more information.

VII. Disposing of Your Biocontainer Assembly

There are various disposal options for biocontainer assemblies. Based on your institution's procedures and practices and compliance with local regulations, the appropriate method of disposal should be determined.

VIII. References

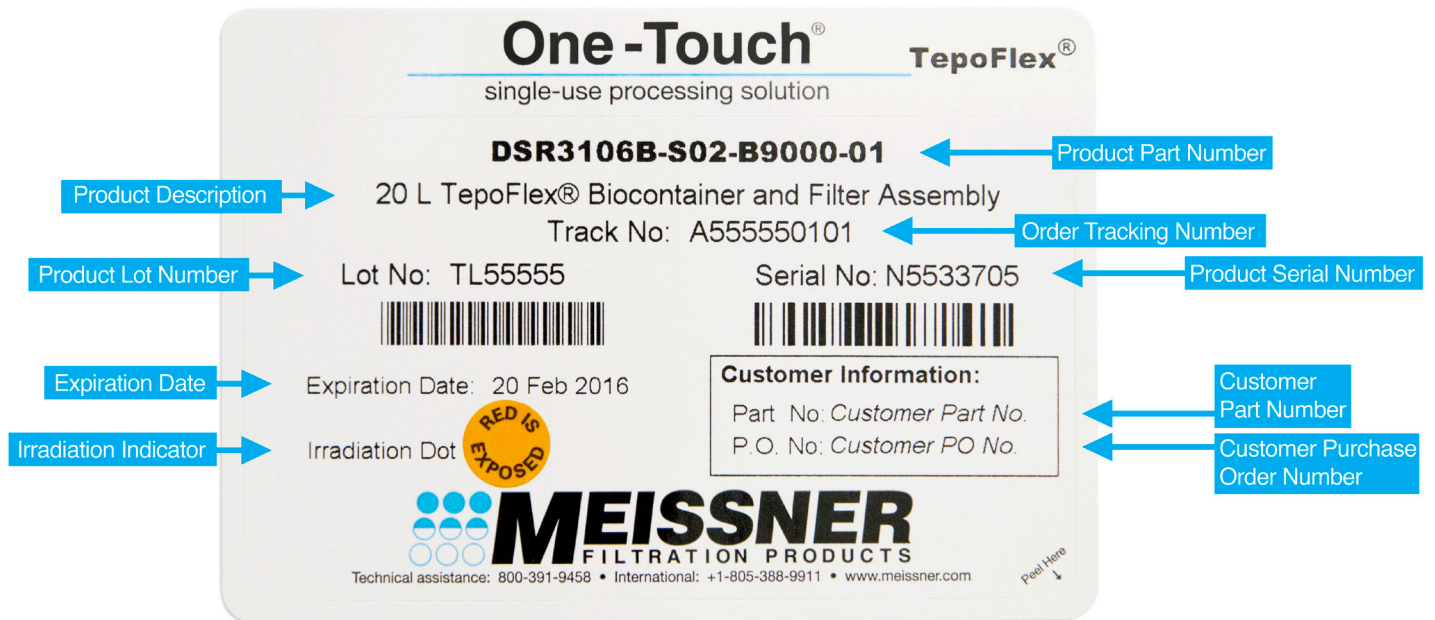
1. Meissner Filtration Products, Inc. (2009) “One-Touch® Biocontainer Deployment for FlexStation® 100-200 ROCs”, Technical Bulletin (TBOT06), November 2009.
2. Meissner Filtration Products, Inc. (2010) “One-Touch® Biocontainer Deployment – FS0500”, Technical Bulletin (TBOT07), October 2010.
3. Meissner Filtration Products, Inc. (2011) “One-Touch® FlexFill® Deployment and Cap Installation”, Technical Bulletin (TBOT09), August 2011.
4. Meissner Filtration Products, Inc. (2012) “One-Touch® Dual Biocontainer Stand & Accessories”, Technical Bulletin (TBOT10), March 2012.
5. Meissner Filtration Products, Inc. (2012) “One-Touch® QuaDrum®”, Technical Bulletin (TBOT12), March 2012.

IX. Appendices

A. Sample Case and Product Labels



Case Label



Product Label

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